



UNITED STATES PATENT AND TRADEMARK OFFICE

clu
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,273	12/09/2003	Laval Chan Chun Kong	VIRO-6	2533

23599 7590 08/31/2006

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,273

Applicant(s)

CHAN CHUN KONG ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 10-14, 16, 17 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 15, 18 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

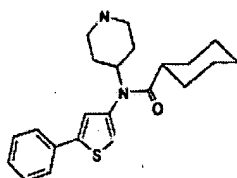
Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

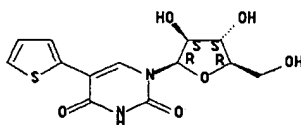
Art Unit: 1625

DETAILED ACTION

1. Applicant's election with traverse of group I, claims 9, 18 in the reply filed on Jun 21, 2006 is acknowledged. The traversal is on the ground that the examiner seeks to restrict within a single claim that has a common core. This is not found persuasive because the two groups although attempted by attorney to be placed in one claim, does not share common core or common utility. For group I compounds, which are described being "prodrug" of parent drug which has the core as:



and being prodrug it must not have antiviral activity (see Bungaard p.1) unless it is hydrolyzed to the "drug". While the group II compounds have the core as:



and this core is evidenced by the prior art (see CA 118:169519) has antiviral activity.

Therefore, group I and group II not only do not share common core, they do not share common utility. The placing them all in one claim is improper Markush grouping and the restriction is proper. See MPEP §803.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 9 and 18, and claims 1-8, 15 reading on the elected compounds and newly added claim 23 are examined. Claims 1-8, 15 remaining compounds and claims 10-14, 16-17, 19-22 are withdrawn from consideration being drawn to the nonelected invention per 37 CFR 1.142(b).

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1625

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 18, 23 and 1-8, 15 reading on the elected compounds are rejected under 35

U.S.C. 103(a) as being unpatentable over Chan Chun Kong et al. US 6,881,741.

Determination of the scope and content of the prior art (MPEP §2141.01)

Chan Chun Kong '741 generically disclosed the claimed compounds see claim 1, and examples of compound 573 287, 563-567.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the Chan Chun Kong '741 compounds is that the instant claims are more limited in the Markush elements. The full scope of the claims have been clearly enabled being guided by the well exemplified compounds with picking and selecting Markush attributes in the well delineated examples.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art in possession of the Chan Chun Kong '741 is in possession of the more limited scope of the instant claims especially, the instant claims being drawn to W being alkoxy and amino acid esters see examples of compound 573 287, and 563-567. There is nothing unobvious in picking some among many. In re Lemin 141 USPQ 814.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1625

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

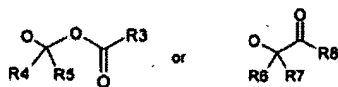
Claims 9, 18, 23 and 1-8, 15 reading on the elected compounds are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan Chun Kong et al. US 6,881,741 in view of Bundgaard.

Determination of the scope and content of the prior art (MPEP §2141.01)

Chan Chun Kong et al. '741 disclosed the instantly claimed compounds as delineated supra.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference of the broaden scope of "W" being the other Markush elements in addition to the alkoxy, are prodrug preparation of the free carboxylic acid of the Chan Chun Kong '741 compounds. Prodrug preparation is a resolution of delivery problem (see Bundgaard p.1), thus, is prima facie obvious modification of a known drug (see p.1). The particular design such as the



two structure: are well know modification suggested by Bungeard to be suitable prodrugs for carboxyl containing drugs (see p.3-5).

Finding of prima facie obviousness—rational and motivation (MPEPS2142-2143)

One having ordinary skill in the art in possession of the above references would be in possession of the drug and its prodrug forms knowing that the prodrug modification as suggested by the prior art having beneficial property in solving delivery problems especially in drugs containing carboxyl groups. The modification of a known drug using attributes well delineated by the prior art to be operable and expected to operate in solving problem is prima facie obvious.

4. Claims 1-9, 15, 18, 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-174 of U.S. Patent No. 6,881,741. Although the conflicting claims are not identical, they are not patentably distinct from each

Art Unit: 1625

other. Or, alternatively, claims 1-9, 15, 18, 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-174 of U.S. Patent No. 6,881,741 in view of Bundgaard.

The finding of prima facie obviousness of the instant claims and the prior art compounds have been delineated supra. The same rational also applies here and hereby incorporated by reference and based on the claims guided by the explicitly guided species of compounds 573 287, 563-567.

There is no good reason that the narrower scope of the compounds with the expected prodrug preparation would need unreasonable prolong of exclusivity since the based compound and its obvious prodrug variation in ester and amino esters have been generically issued.

5. Claims 1-9, 15, 18, 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-101 of copending SN 10/730,272. Although the conflicting claims are not identical, they are not patentably distinct from each other. Or, alternatively, claims 1-9, 15, 18, 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-101 of copending SN 10/730,272.

The SN 10/730,272 are claiming a smaller genus of the free carboxylic acid drugs (W=OH) of the instantly claims prodrugs. The same rational for finding prima facie obviousness of the instant claims and copending claims as delineated supra are also applicable here and hereby incorporated by reference.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1625

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).


6. No claims allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Aug. 28, 2006


Celia Chang
Primary Examiner
Art Unit 1625